Amendment to the Specification

In the Specification:

Please amend the specification as follows:

On Page 1, the paragraph beginning at line 14 should be replaced with the following.

The use of simulated physiological structures for training medical students and providing skill training for practicing physicians is widespread. Although cadavers have traditionally been beneficially employed for this purpose, cadavers are not always readily available and are not well suited for all types of training.

On Page 2, the paragraph beginning at line 1 should be replaced with the following.

The need for such simulators should not be underestimated, because they can provide valuable training that will lead to more effective treatment of patients. For example, medical personnel who administer emergency trauma care can greatly benefit from the training achieved using a simulated physiological structure. Training in administering trauma surgical procedures, which include those procedures that are usually performed on a person who has experienced some form of severe and often ~~life threatening~~ life-threatening injury, is particularly beneficial. Such procedures may aid in the diagnosis of a condition, or may provide immediate life-saving care until more complete medical treatment is available. The procedures may include clearing a blocked airway or draining accumulations of fluids from internal organs. While appearing to be simple procedures, if these procedures are performed improperly, the result can worsen the patient's condition, placing the patient at an even greater peril of death. By their nature, trauma procedures are usually performed under emergency conditions in which the person administering the care is under time-related stress. It is therefore useful to provide training methods and apparatus to fully prepare students and physicians in these procedures, so that they can be performed without delay, under stressful conditions.

On Page 6, the paragraph beginning at line 18 should be replaced with the following.

Some embodiments further include a sensor coupled with the evaluation circuit, and the evaluation circuit is configured to provide the signal when the sensor indicates a change in a physical

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property has been detected. Beneficial sensors will include temperature sensors and chemical sensors.

On Page 7, the paragraph beginning at line 7 should be replaced with the following.

In another embodiment, the conductive elastomer is configured to achieve a touch sensitive circuit. Touch sensitive circuits can be achieved using circuits sensitive to changes in temperature, resistance, capacitance,[[.]] and radio reception. Some touch sensitive circuits can be configured to be pressure sensitive as well, such that a magnitude of pressure applied can be determined.

On Page 11, the paragraph beginning at line 15 should be replaced with the following.

FIGURES 10A-10D schematically ~~illustrates~~ illustrate embodiments of evaluation circuits in accord with the present invention;

On Page 11, the paragraph beginning at line 19 should be replaced with the following.

FIGURES 12A-12D schematically ~~illustrates~~ illustrate different embodiments for processing an indication from one of the evaluation circuits of FIGURES 10A-10D and 11A-11E;

On Page 14, the paragraph beginning at line 14 should be replaced with the following.

Conductive elastomer-based evaluation circuits incorporated into simulated physiological structures can be used in a variety of different ways. Three significant uses include collection of data which is stored for later use, collection of data to be processed to provide some contemporaneous feedback (such as a visual or an audible indication that a procedure has been performed correctly or incorrectly, provided to a trainee, a proctor, or both), and collection of data which is analyzed and may be used to trigger a simulated physiological response in the simulated physiological structure (i.e. a change in a simulated heartbeat, a simulated muscular response, a change in a simulated respiratory rate, etc., implemented by controlling a servo or pump). In a relatively simple implementation, the electrical signal obtained from a conductive elastomer-based evaluation circuit is used to provide simple feedback, such as lights that turn on or off, and/or the activation of aural or verbal prompts or cues. In some implementations the metric is simply whether a current is flowing through the circuit. More complex circuits can be configured to determine a position of a simulated

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medical instrument (such as a needle, a catheter, an endoscope, or other tool) during each phase of a simulated procedure, to respond to touch, to measure pressure (useful for determining if the force applied by a trainee in ~~handing~~ handling a structure such as an organ is appropriate), and/or to measure impedance changes throughout a circuit. The use of appropriate sensors in a conductive elastomer-based evaluation circuit will enable changes in physical properties of the model to be evaluated. For example, some medical procedures involve the application of chemicals (i.e., drugs), heat, cold, and/or electromagnetic radiation to tissue or other physiological structures. Appropriate sensors can be incorporated into conductive elastomeric-based evaluation circuits so that feedback relating to the physical property change can be gathered. The electrical signal from the evaluation circuit can be manipulated and analyzed by logical processing elements, such as computers. Using a computer enables data provided by such evaluation circuits to be immediately processed and displayed, immediately processed but stored for later use, stored for later processing, compared to similar data, electronically distributed to other users in a network, or any combination thereof.

On Page 19, the paragraph beginning at line 10 should be replaced with the following.

Beginning with the uppermost and outermost layer, a composite layer 222 simulates human skin. For the purposes of this description, skin is considered a membranous layer. Composite layer 222 includes a silicone blend 202 and a reinforcing silicone-coated fibrous layer 204, and preferably a pigment. As is generally known in the elastomer arts, any of a number of suitable pigments for silicone blends can be used to visually represent different layers. The silicone used in the invention is preferably obtained from Silicones, Inc. of High Point, North Carolina, under the mark XP-153A. Preferably, the silicone is mixed with a thinning agent, also obtained from Silicones, Inc., under the mark GI THINNER™. The volume ratio of silicone to thinner may be adjusted more or less to arrive at a suitable hardness and texture, but preferably, the volume ratio is between about 2:1 of silicone to thinner and about 10:1 of silicone to thinner. Techniques for molding and curing items of silicone and thinner are generally known by those of ordinary skill in the art and need not be set forth herein to enable the present invention. Although silicone has been found to perform best, other elastomeric materials, such as latex, may alternatively be used. Silicone-coated fibrous layer 204 is preferably pre-formed and cured and is then applied below or atop an uncured silicone formulation while in the mold. As the silicone formulation cures, the pre-formed fibrous layer is

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bonded thereto. However, the silicone-coated fibrous layer need not be bonded to the silicone blend layer. The silicone-coated fibrous layer 204 imparts a realistic resistance to cutting, similar to the resistance of real human skin. The fibrous layer is preferably made of a nylon mesh material. However, a felt material will perform equally well under some circumstances. Any number of synthetic or natural fibers will also be effective for use in this layer, to some degree. For instance, in the abdomen area, felt is the preferred fibrous material for the silicone-coated fibrous layer. While the skin is intended to be a very close approximation to actual human skin, it is to be recognized that real human skin includes numerous strata of virtually imperceptible differences. However, the simulated skin of the present invention closely represents the epidermis and dermis of actual human skin. Preferably, a pigment is added in the silicone blend to color the skin similar to human skin. Also, composite skin layer 222 including the fibrous layer 204 is about 2 to about 4 millimeters thick. While a preferred embodiment of skin layer 222 includes a reinforcing silicone-coated fibrous layer 204, the ~~user~~ use of more reinforcing layers are contemplated.

On Page 26, the paragraph beginning at line 16 should be replaced with the following.

Referring to FIGURE 5, in the area of the neck region, surgical trainer 100 also includes a simulated thyroid cartilage 142, a simulated cricoid cartilage 144, and a simulated cricothyroid ligament 146. Cricoid cartilage 144 and thyroid cartilage 142 are molded of suitable thermoplastic or polymeric materials. Preferably, a rubber such as POLY-FAST 72-40 RTV™ liquid rubber, available from the Polytek Development Corporation of Easton, Pennsylvania can be used to fabricate these pieces. In FIGURE 9, a more detailed view of these structures is shown. These structures form part of the respiration system and include a trachea, modeled here by a plastic tube 148 of similar consistency and resistance to cutting, as exhibited by an actual human trachea. Trachea 148 is connected to the cricoid cartilage 144, which is thicker and stronger than thyroid cartilage 142. Thyroid cartilage 142 is the largest of the laryngeal cartilages (others have been omitted for clarity) and includes a laryngeal prominence 150, better known as the Adam's Apple, and the thyroid notch. In a trainer modeled after a female, the laryngeal prominence will be almost imperceptible. Cricothyroid ligament 146 is represented in this Figure as being integral with the trachea member, but in a human, actually connects the cricoid cartilage 144 and thyroid cartilage 142. The cricothyroid ligament is modeled by a suitable plastic tubing or hose of similar consistency and

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resistance to cutting as an actual human cricothyroid ligament. The thyroid and cricothyroid cartilages are modeled from a unitary molded piece, which has an aperture traversing longitudinally along the mid axis, so as to fit through trachea 148.

On Page 31, the paragraph beginning at line 4 should be replaced with the following.

Trainer 100 also enables a trainee to practice pericardiocentesis. Pericardiocentesis is another trauma procedure usually done to evaluate the status of a chronic or recurrent pericardial effusion (fluid in the pericardial sac), as a result of trauma to the chest. It may also be done to relieve cardiac tamponade (compression of the heart from an accumulation of fluid within the pericardial sac). The procedure includes the steps of puncturing the skin 1- 2 centimeters inferior and to the left of the xiphochondral junction, at a 45 degree angle to the skin. The needle is advanced ~~cephalad~~ cephalad, aimed toward the tip of the left scapula. When the needle tip enters the blood-filled pericardial sac (pericardium), blood within the pericardial sac can be withdrawn. This part of the procedure is simulated in trainer 100 by filling pericardium 162 with simulated blood. A complication of this procedure includes laceration of the myocardium or wall of the heart, which is simulated in trainer 100 by providing simulated heart 164 filled with a different colored simulated blood. If blood from simulated heart 164 is aspirated, the trainee will recognize that the myocardium has been lacerated (or punctured) by the change in blood color. Thus, the trainee can experience this complication resulting if the needle is inserted at the incorrect location. Another complication might be puncturing a lung, which can be simulated on trainer 100, because the trainer provides an inflatable lung 158.

On Page 36, the paragraph beginning at line 21 should be replaced with the following.

In yet another embodiment, a conductor 338a is placed in ~~gap 336to~~ gap 336 to complete the circuit. With respect to the blood vessels/intestines noted above, rather than physically moving adjacent ends of such a simulated structure so that the opposed ends are coupled together, conductor 338a represents an additional section of a blood vessel or an intestine that is placed in the gap (and sutured or otherwise coupled to the other portions of the simulated physiological structure) to complete the circuit. In some embodiments, conductor 338a is a probe or instrument, that when properly employed in a simulated medical procedure will complete the circuit. For embodiments in

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which conductor 338a is a probe or instrument (as opposed to a portion of a simulated physiological structure), the configuration of conductor 338a depends on the simulated medical procedure to be evaluated. In such cases, conductor 338a can be any metallic medical instrument, such as a syringe needle or a scalpel.

On Page 39, the paragraph beginning at line 3 should be replaced with the following.

FIGURE 11A schematically illustrates an evaluation circuit 344 that includes a pressure sensitive transducer 343, which as will be described in greater detail below, can be beneficially incorporated into a simulated physiological structure. Such piezoelectric circuits are well known and generate an electrical potential in response to applied mechanical force. Evaluation circuit 344 is configured so that when a probe 338d is utilized to properly execute a simulated medical procedure (and in doing so, applies a force to pressure sensitive transducer 343), an electrical current is generated that can be used to produce a feedback signal indicative of the level of pressure applied. Note that while piezoelectric materials are not elastomeric, a portion of circuit 344 is formed of conductive elastomers. As discussed above, elastomeric materials can be employed to realistically simulate many physiological elements, such as skin, tissue, membranes, fat, muscle ~~an~~ <u>and</u> organs. Piezoelectric materials are generally hard. There are physiological elements that can be simulated using hard materials, such as bone and cartilage. Thus, one implementation of circuit 344 could be a simulated bone, with piezoelectric material simulating a portion of the bone structure, and conductive elastomers simulating muscle and other tissue attached to and disposed adjacent to the bone. However, the force can be transmitted using a fluid, so that the tactile sensation associated with applying the force does not correspond to the feel of a relatively hard pressure sensitive transducer. Thus, if the simulated medical procedure being evaluated is manual cardiac massage, a pressure sensor sensing a pressure of a fluid in the simulated heart can produce the feedback signal indicative of the applied pressure, to indicate if the person applying the pressure to the simulated heart is performing the procedure properly and within acceptable limits. Also, other types of pressure transducers, such as variable capacitance and variable resistance transducers, are available that are less detectable by touch and can be used for sensing applied force or pressure.

On Page 41, the paragraph beginning at line 22 should be replaced with the following.

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FIGURE 11E illustrates a conductive elastomer-based evaluation circuit 361 that includes a capacitance sensitive switch 363. In a capacitance sensitive switch, an inherent or baseline charge of a capacitor is changed. Depending on the configuration of the capacitance sensitive switch, the baseline charge can be changed by a conductive object (which adds or removes charge from the capacitance sensitive switch), or by a non conductive object that changes the properties of the dielectric in the capacitor. Capacitance sensitive switches or sensors can be configured in several ways. In some configurations, at least one of the two electrodes of a capacitor are movable, and the sensor/switch responds to the increase or decrease of the dielectric gap between the electrodes (which changes the baseline charge of the capacitor). In other configurations the positions of the electrodes are fixed, and a nonconductive material is introduced into the dielectric gap between the electrodes, which changes the properties of the dielectric gap, again resulting in a change from the baseline charge of the capacitor. In yet another configuration, the positions of the electrodes are fixed, and a conductive material is placed in contact with one of the plates, yet again changing the baseline state of the capacitor. Thus depending on the configuration of capacitance sensitive switch 363, probe 365 can be a conductor or an insulator. Note that capacitance can be used to measure pressure, as well as responding to touch. As described above, when the dielectric gap between two plates of a capacitor changes, the change in capacitance can be measured. A pressure sensitive circuit can be configured such that as pressure is applied to one plate of a capacitor by a simulated instrument, that plate moves relative to the other plate of the capacitor, effectively changing the baseline capacitance of the capacitor by changing the dielectric gap. The more pressure is applied, the smaller the gap becomes, and the larger the change. Of course, the simulated instrument must be an insulator, or contact by the instrument to the capacitor plate will in and of itself change the baseline capacitance. To respond to pressure applied by a user's fingers or a conductive simulated instrument, an insulator layer (for example, a non conductive elastomeric layer of sufficient thickness to block induction) can be placed between the movable capacitor plate and a trainee's finger or the conductive simulated surgical instrument. Because capacitance sensitive circuits measure the change in capacitance, and capacitance can be changed based on a function of a distance between a capacitor and an object affecting the baseline charge of the capacitor, capacitance sensitive switches/sensors can be used to determine proximity. For example, as a simulated instrument is brought closer and closer to a capacitance sensitive circuit, the change in the baseline capacitance increases. Such capacitance

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sensitive circuits can be used to determine the degree of proximity between the circuit and an object. Such capacitance sensitive circuits are therefore very useful in enabling a conductive elastomer-based evaluation circuit to provide feedback about the proximity (and the degree of proximity) of an object relative to the circuit. As with resistance sensitive switches, capacitance sensitive switches have also been used to determine a coordinate position in touch sensitive display implementations. When a user touches such a touch sensitive display, some of the charge from the display is transferred to the user, so the charge on the capacitive layer decreases. This decrease is measured in circuits located at each corner of the display. A computer calculates, from the relative differences in charge at each corner, exactly where the touch event took place. If desired, such a position sensitive capacitance sensitive switch can be implemented in a conductive elastomer-based evaluation circuit in accord with the present invention. As discussed above, portions of circuit 361 may be implemented using conventional circuit elements. To achieve a realistic model, preferably portions of circuit 361 that can be seen or felt by a trainee will be implemented using conductive elastomers, to enhance the training experience.

On Page 43, the paragraph beginning at line 15 should be replaced with the following.

As noted above, FIGURES 12A-12D schematically illustrate different embodiments for utilizing the current flowing in the circuits described above to provide feedback indicative of ~~the~~ whether a simulated medical procedure is being properly performed, or indicative of the quality of the performance. In FIGURE 12A, an electrical current flowing in the evaluation circuit is used to energize a light source 346a comprising indicator 334. The light source can be a light emitting diode (LED) or other type of light emitting device or lamp. A LED or other solid state light source is preferable, since such devices require less electrical power than do conventional incandescent light sources.

On Page 43, the paragraph beginning at line 24 should be replaced with the following.

In FIGURE 12B, indicator 334 comprises a circuit 348, which includes a power source 350, a light source 346b, and an electronic switch 352, which is used to open and close circuit 348. Electronic switch 352 is normally in an open state, and thus, light source 346b is not illuminated. When the evaluation circuit provides a potential to trigger electronic switch 352, the electronic switch

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changes to a closed state, completing circuit 348 and causing the light source to produce light. Light source 346b is an LED, or lamp. Note that light source 346b can be an incandescent source or other higher current light emitting device without requiring that the evaluation circuit carry the current needed to energize the light source, because light source 346b in circuit 348 is energized by separate power source 350. Of course, electronic switch 352 can be configured to be in the closed state until a trigger potential is received from the evaluation circuit, so that the light source remains energized until the evaluation circuit produces a potential indicative of the proper execution of a simulated medical procedure.

On Page 46, the paragraph beginning at line 24 should be replaced with the following.

Each of conductive elastomers 374, 376, and 378 is coupled to a different light source. Conventional wire conductors can be used for this purpose, or smaller segments of conductive elastomers. Conductive elastomer 378 is coupled to a green light 380a, conductive elastomer 376 is coupled to an amber light 380b, and conductive elastomer 374 is coupled to a red light 380c. Each conductive elastomer is labeled R, A, or G to indicate the color of light to which the conductive elastomer is electrically coupled. The other terminal of each light 380a-380c is then electrically coupled to one terminal of a battery 370. An opaque elastomeric layer 379 is placed over each conductive elastomer, so that the individual conductive elastomers ~~were~~ are not visibly apparent.

On Page 47, the paragraph beginning at line 20 should be replaced with the following.

It should be understood that it would be straightforward to modify circuit 368 to include discrete conductive elastomers that are shaped as vertical strips (like conductive elastomer 378) for monitoring more regions along the X-axis. Thus, the vertical portions of conductive elastomers 374 and 376 to the left of conductive elastomer 378 would represent discrete conductive elastomers that monitor corresponding regions, and the vertical portions of conductive elastomers 374 and 376 to the right of conductive elastomer 378 would similarly represent discrete conductive elastomers that monitor corresponding discrete regions along the X-axis. Each individual discrete conductive elastomer would be coupled to a light source of a different color (or to lights in different corresponding positions along an array of light sources – not shown), so that the light source would indicate whether the probe was placed to the left or right of the correct position along the X-axis (i.e.

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to the left or right of conductive elastomer 378), and the extent of the deviation from the correct position. Of course, instead of coupling each conductive elastomer to a light, the elastomers can be connected to a different indicator, such as a meter, or a computing device or processor that keeps track of which conductive elastomer is contacted by the energized probe. It should also be understood that multilayer configurations with conductive elastomer bars extending horizontally can be used to determine the accuracy of the probe penetration along the Y-axis, and thus the configuration of circuit 368 merely represents one potential embodiment. Any configuration of conductive elastomers employed for a commercial application of the present invention will be selected to evaluate specific simulated medical procedures. Thus, the specific configuration of the evaluation circuit will depend on the simulated procedure ~~be~~ being evaluated, and the simulated physiological structure with which the evaluation circuit is employed. Several examples are described below.

On Page 60, the paragraph beginning at line 1 should be replaced with the following.

Simulated bone 432 includes a fragment 436a separable from a remainder 436b. A procedure often employed to rejoin a fragment to the remainder is to drill a hole passing through the fragment and into the remainder, and to insert a rod or screw into the hole to join the fragment to the remainder ~~together~~ while the ~~bodies'~~ body's healing processes fuse the fragment and remainder together. Simulated bone 432 thus includes an evaluation circuit 438, configured to evaluate whether a hole drilled by a person performing the procedure is properly positioned. Conductive elastomers comprising evaluation circuit 438 are disposed along the preferred drill path through the fragment and remainder of the bone and the drill bit completes a circuit (or breaks a circuit) formed by the conductive elastomers to provide an indication that the drill is properly positioned to drill the hole for the rod.

On Page 77, the paragraph beginning at line 3 should be replaced with the following.

Network 512 includes major branches(shown in bold) 512a that are coupled to each smaller portion of the network, and branches 512a are coupled to port 514. Each simulated physiological structure within human patient simulator 510 (i.e., lungs, organs, joints, tissue, etc.) preferably includes conductive elastomer-based evaluation circuits that are coupled to a major branch, so that

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feedback from the structures can be collected via port 514. Port 514 and major branches 512a can be used to provide bi-directional signal flow. In some embodiments, simulated lungs will be coupled to a pump that causes the lungs to inflate and deflate. In other embodiments, servo motors will be incorporated into joints or other simulated ~~structure~~ structures to simulate voluntary and involuntary movements (i.e. blinking, breathing, flushing). Thus, port 514 and major branches 512a can be used to distribute control signals from processor 516 to such controllable components (not separately shown in FIGURE 24). A deluxe human patient simulator includes simulated physiological structures having conductive elastomer-based evaluation circuits, each coupled to network 512, so that data relating to many different types of simulated procedures can be collected and analyzed.

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